IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9060

Bartle, J. May 8, 2013

Celeste A. Barker ("Ms. Barker" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claims for Matrix Compensation Benefits ("Matrix Benefits").[2]

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney completes Part III if claimant is represented.

In April, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, A. Razzak Tai, M.D., F.A.C.C., F.A.C.C.P., F.A.C.A., F.A.H.A., F.S.C.I.A.[3] Dr. Tai is no stranger to this litigation. According to the Trust, he has attested to at least 1,512 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated December 12, 2002, Dr. Tai attested in Part II of

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2. (...continued)
serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Ms. Barker has submitted two Green Forms to the Trust for processing, one in September, 2002 and one in April, 2003. Each of these claims is currently before the court. As the April, 2003 Green Form was processed first, we outline the history of that claim first here.

Ms. Barker's Green Form that claimant suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $567,341.[5]

In the report of claimant's echocardiogram, Dr. Tai noted that Ms. Barker had mitral regurgitation of 30%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In February, 2006, the Trust forwarded the claim for review by Zuyue Wang, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Wang concluded that there was no reasonable medical basis for the attesting physician's finding

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4. Dr. Tai also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Trust disputes that there is a reasonable medical basis for Dr. Tai's representation that claimant has an abnormal left atrial dimension and a reduced ejection fraction in the range of 50% to 60%, each of which is one of the complicating factors needed for a Level II claim, we need not resolve these issues given our determination with respect to claimant's level of mitral regurgitation.

that claimant had moderate mitral regurgitation. Dr. Wang explained, "The RJA/LAA ratio is less than 20%. The RJA traced should not include the area of low velocity flow."

Based on the auditing cardiologist's findings, the Trust issued a post-audit determination denying Ms. Barker's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[6] In contest, claimant argued that there was a reasonable medical basis for Dr. Tai's representation of moderate mitral regurgitation because three different cardiologists, based on echocardiograms performed in 2002, concluded that Ms. Barker had moderate regurgitation. Ms. Barker had four echocardiograms. The first occurred on September 19, 1997 and was signed by Allan L. Anderson, M.D. It indicated that claimant had mild mitral regurgitation. The remaining three were performed on: July 18, 2002, signed by Andrew E. Dick, M.D., F.A.C.C.; December 12, 2002, signed by Dr. Tai; and December 20, 2002, signed by Paulo A. Ribeiro, M.D. These three echocardiograms indicated that claimant had moderate mitral regurgitation.

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6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

The Trust then issued a final post-audit determination, again denying Ms. Barker's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to Show Cause why Ms. Barker's claim should be paid. On August 21, 2006, we issued an Order to Show Cause and referred the matter to the Special Master for further proceedings. See PTO No. 6477 (Aug. 21, 2006). Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on December 27, 2006.

In support of this claim, Ms. Barker repeats the argument she made in contest, namely, that there was a reasonable medical basis for Dr. Tai's representation of moderate mitral regurgitation because four different cardiologists, based on echocardiograms performed in 1997 and 2002, concluded that she had mild or moderate regurgitation. Claimant also argues that the difference in the determinations of her physicians and the auditing cardiologist fall within the reasonable medical basis standard. Finally, Ms. Barker identifies a number of alleged procedural errors by the Trust in connection with her claim: (1) claimant received a telephone call, rather than a writing, requesting that she submit the echocardiogram associated with her

claim; (2) the Trust informed claimant it had requested a Medical Practice Questionnaire from her in 2003 when it had not; (3) the Trust should not have processed her second Green Form; and (4) the Trust "contaminated" her claim file by sending "multiple sources of echocardiographic evidence related to completely separate and independent Green Forms."

In response, the Trust argues that it acted in good faith in processing Ms. Barker's claim and that it processed her most recent Green Form first because that was the Trust's policy absent a clear intention of the claimant to the contrary. The Trust also contends that Ms. Barker's reference to other echocardiograms does not establish a reasonable medical basis for Dr. Tai's representation of moderate mitral regurgitation and does not meet claimant's burden because her echocardiogram reports do not address Dr. Wang's specific findings at audit, that is, that Dr. Tai's finding of moderate mitral regurgitation was based on an overtraced RJA that included low velocity flow.

In September, 2002, claimant submitted another completed Green Form to the Trust signed by her attesting physician, Dr. Dick. He also is no stranger to this litigation. According to the Trust, he has attested to at least 305 Green Forms on behalf of claimants seeking Matrix Benefits. Based on claimant's June 12, 2002 echocardiogram, Dr. Dick attested in Part II of claimant's Green Form that Ms. Barker suffered from moderate mitral regurgitation and an abnormal left atrial

dimension.[7] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $590,261.[8]

In the report of claimant's echocardiogram, Dr. Dick noted that claimant had mitral regurgitation of 40%. Again, under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In October, 2007, the Trust forwarded the claim for review by Irmina Gradus-Pizlo, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Gradus-Pizlo concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because the echocardiogram demonstrated only mild mitral regurgitation. Dr. Gradus-Pizlo explained, "Color persistence is too high. Jet area measurements include non-turbulent flow."

Based on the auditing cardiologist's finding, the Trust issued a post-audit determination denying Ms. Barker's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims

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7. Dr. Dick also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition is not at issue in this claim.

8. As the Trust does not contest Dr. Dick's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue in this claim is Ms. Barker's level of mitral regurgitation.

("Audit Rules"), claimant contested this adverse determination.[9] In contest, as with her other claim, Ms. Barker argued there was a reasonable medical basis for the attesting physician's representation of moderate mitral regurgitation because four different cardiologists concluded that Ms. Barker had mild or moderate regurgitation.

The Trust then issued a final post-audit determination, again denying this claim. Claimant disputed the final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to Show Cause why Ms. Barker's claim should be paid. On August 21, 2008, we issued an Order to Show Cause and referred the matter to the Special Master for further proceedings. See PTO No. 7925 (Aug. 21, 2008). Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on December 18, 2008, and claimant submitted a sur-reply on January 18, 2009.

In support of her claim, Ms. Barker repeats her argument that the echocardiograms from 2002 establish a

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9. As this claim was placed into audit after December 1, 2002, there also is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

reasonable medical basis for Dr. Dick's finding of moderate mitral regurgitation. Claimant also reiterates that the Trust intentionally handled Claimant's previous claim "in an out of order fashion."

In response, the Trust argues that claimant did not address Dr. Gradus-Pizlo's findings that the June 12, 2002 echocardiogram demonstrates unacceptably high color persistence and that "measurements of the RJA included 'non-turbulent flow.'" The Trust further asserts that the additional echocardiogram reports submitted by claimant do not provide a reasonable medical basis for a representation based on her June 12, 2002 echocardiogram. Finally, the Trust contends that claimant's argument regarding the order in which her claims were processed is irrelevant to her burden of proof in these proceedings.

In her sur-reply, claimant again argues that the echocardiogram conducted by Dr. Ribeiro constitutes prima facie evidence in support of her claim. Ms. Barker further contends that because of alleged processing errors, the auditing cardiologist did not review all of her medical information.

The issue presented for resolution of these claims is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physicians' findings that she had moderate mitral regurgitation. See Audit Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Forms that are at issue, we must affirm the Trust's final determinations and may

grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer(s), we must enter an Order directing the Trust to pay the claim(s) in accordance with the Settlement Agreement. See id. Rule 38(b).

Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor[10] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiograms of June 12, 2002, December 12, 2002, and December 20, 2002 and determined that there was no reasonable medical basis for finding moderate mitral regurgitation on these echocardiograms because each of them demonstrated only mild

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10. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

mitral regurgitation. With respect to the June 12, 2002 echocardiogram, Dr. Vigilante explained:

> On the study of June 12, 2002, the mitral valve appeared normal with normal leaflet excursion.... There was a thin posterolaterally directed jet of mitral regurgitation seen in the real-time images in the parasternal long axis and apical views. In the mid portion of systole, the largest representative RJA measured no more than 2.5 cm2 in the apical four chamber view and less than this in the apical two chamber view. The LAA was determined to be 14.6 cm2. Therefore, the largest representative RJA/LAA ratio was no more than 17%. The RJA/LAA ratio never approached 20%. Most of the cardiac cycles demonstrated RJA/LAA ratios less than 15%. The sonographer measured the LAA to be 14.59 cm2 which was accurate. However, the sonographer inaccurately measured the RJA. The measurements were 4.62 cm2 and 5.85 cm2 in the apical four chamber view and 4.41 cm2 in the apical two chamber view. These measurements were inaccurate and contained a great deal of low velocity and non-mitral regurgitant flow which was accentuated by the inappropriately high color gain settings and borderline low Nyquist limit settings. The correct RJA/LAA ratio was no more than 17%.

With respect to the December 12, 2002 echocardiogram, Dr. Vigilante determined:

> The study of December 12, 2002 demonstrated normal appearance of the mitral valve.... Visually, mild mitral regurgitation was seen with a posterolaterally directed jet noted on a parasternal long axis and apical views. I determined that the left atrial area was 15.5 cm2. The largest representative RJA in the apical four chamber view was 2.4 cm2. The largest representative RJA in the apical two chamber view was less than 2 cm2. Therefore, the largest representative RJA/LAA ratio was less than 16% qualifying for mild mitral regurgitation. The RJA/LAA ratio never approached 20%. Most of the RJA/LAA ratios

> were less than 15%. The sonographer measured the LAA to be 15.37 cm2 which was similar to my measurement. However, the sonographer measured multiple inaccurate RJA's. The sonographer RJA determinations on this study were 4.08 cm2, 4.05 cm2, 4.06 cm2, 3.81 cm2, and 4.84 cm2. All of these determinations were comprised of a great deal of low velocity, non-mitral regurgitant flow.

Finally, with respect to claimant's December 20, 2002 echocardiogram, Dr. Vigilante observed that:

> I reviewed the patient's echocardiogram of December 20, 2002.... Excessive color gain was noted on Doppler evaluation. In spite of the inappropriate conduct of the study, I was able to evaluate the mitral regurgitant jet in the mid portion of systole.... A mild postero-laterally directed jet of mitral regurgitation was noted on real-time evaluation. I digitized the cardiac cycles in the apical two and four chamber views in which the mitral regurgitant jet was demonstrated. I determined that the LAA was 16.2 cm2 in the apical four chamber view and 15.2 cm2 in the apical two chamber views. I determined that the largest representative RJA was 2.5 cm2 in the apical four chamber view and 1.8 cm2 in the apical two chamber view. Therefore, the largest representative RJA/LAA ratio in the apical four chamber view was 15% and the largest representative RJA/LAA ratio in the apical two chamber view was 12%. The RJA/LAA ratio never approached 20%. Most of the RJA/LAA ratios were less than 10%. The sonographer measured RJA's of 5.54 cm2 and 5.65 cm2 in the apical four chamber view and 2.53 cm2 and 4.51 cm2 in the apical two chamber view. These determinations were completely inaccurate and contained a great deal of low velocity, non-mitral regurgitant flow.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not adequately refute the findings of the auditing cardiologists and

the Technical Advisor. Specifically, Dr. Gradus-Pizlo and Dr. Vigilante determined that claimant's June 12, 2002 echocardiogram demonstrated only mild mitral regurgitation. Similarly, Dr. Wang and Dr. Vigilante determined that claimant's December 12, 2002 echocardiogram was diagnostic of only mild mitral regurgitation. Mere disagreement with the auditing cardiologists or the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

We also disagree with claimant that her echocardiograms from June 12, 2002, December 12, 2002, and December 20, 2002 establish a reasonable medical basis for either of her claims. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of claimant's regurgitation." See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002).

Here, Dr. Gradus-Pizlo reviewed claimant's June 12, 2002 echocardiogram and determined that the "[c]olor

persistence is too high" and that the "[j]et area measurements include non-turbulent flow." Dr. Wang reviewed claimant's December 12, 2002 echocardiogram and found that the RJA traced on the echocardiogram inappropriately included an area of low velocity flow. In addition, Dr. Vigilante reviewed claimant's June 12, 2002, December 12, 2002, and December 20, 2002 echocardiograms and determined that the RJA measurements on each of them were inaccurate as they included low velocity and non-mitral regurgitant flow.[11] Claimant did not refute these determinations. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnoses and Green Form answers.

Finally, we reject Ms. Barker's argument that her claims should be paid because the Trust did not comply with the procedural guidelines set forth in the Settlement Agreement and the Audit Rules. None of the processing errors Ms. Barker alleges, even if true, would change our conclusion that there is no reasonable medical basis for her claims.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for the findings of her attesting physicians that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Barker's claims for Matrix Benefits.

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11. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.